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(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Wichai CHERDSHEWASART

Application No.: 10/702,550

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For: EXTRACTS DERIVED FROM PUERARIA
MIRIFICA, BUTEA SUPERBA AND/OR
MUCUNA COLLETTII AND EXTRACTION
THEREOF

Examiner: C. R. Tate

DECLARATION UNDER 35 USC 1.132

MS RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

September 13, 2005

Sir:

I, Dr. Wichai CHERDSHEWASART, hereby declare as follows:

I am an Associate Professor in the Department of Biology, Faculty of Science, Chulalongkorn University, the first and most famous Thai University. I received my Bachelor of Science Degree in Zoology in 1975, and my Masters Degree in Zoology in 1977.

I became a Master of Science in Molecular Biology in 1986 and obtained my Doctorate, with great distinction in 1991, at the Vrije University, Brussels, Belgium. In 1989 I was awarded the Certificate in Plant Biotechnology the ICRO-Universidad Complutense de Madrid, Spain.

In 1993, I was honored by the Professorship Fund of the Faculty of Science, Chulalongkorn University.

In 1996, I was awarded the Taguchi Prize for outstanding research in the field of biotechnology. I began my research on *Pueraria mirifica* in 1991 and soon thereafter on *Butea Superba*. My research was initiated by traveling all over rural parts of Thailand to search for and select the best, most effective cultivars of these herbs. This was achieved by examining botanical characteristics, chemical analysis, consumption history, toxicology testing, as well as laboratory and clinical trials.

I am the author of 20 articles in international publications, text and method books, proceedings and symposia and also hold the U.S. Patent (U.S. 6,673,377) with one additional patent still pending.

In the present Declaration I have provided Experimental Data which shows that a greater therapeutic effect with respect to erection dysfunction or malfunction can be achieved when utilizing extracts of a combination of *Butea Superba* and *Mucuna Collettii* rather than utilizing those extracts alone. The Experimental Data are detailed here-in-below.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signed this day of _____

Dr. Wichai CHERDSHEWASART

Experimental Data

- When mixing *Butea superba* and *Mucuna collettii* -

1. Preparation of extract of *Butea superba*

100g of the tuber of *Butea superba* was cleansed, dried at 70°C for about 5 hours by use of a hot-air drier, and pulverized. To the resulting plant pieces was added 50mL of a mixture of methanol and water (80/20 v/v), followed by the extraction at 50°C for about 6 hours. After being filtered, the extract was concentrated in a vacuum to remove the solvent. The concentrate was freeze-dried leaving powder of extract of *Butea superba*.

2. Preparation of extract of *Mucuna collettii*

100g of the tuber of *Mucuna collettii* was cleansed, dried at 70°C for about 5 hours by use of a hot-air drier, and pulverized. To the resulting plant pieces was added 50mL of a mixture of methanol and water (80/20 v/v), followed by the extraction at 50°C for about 6 hours. After being filtered, the extract was concentrated in a vacuum to remove the solvent. The concentrate was freeze-dried leaving powder of extract of *Mucuna collettii*.

3. Effect of *Butea superba*, *Mucuna collettii* and combination thereof on male with erection dysfunction upon oral administration

In order to determine whether the extracts of *Butea superba*, *Mucuna collettii* and combination thereof have an effect on erection dysfunction, 180 male patients with erection dysfunction, who were 20~55 years old, were orally administered a placebo, extract of *Butea superba*, extract of *Mucuna collettii*, or combination of extract of *Butea superba* and extract of *Mucuna collettii*. It was used tapioca starch as the placebo.

180 males divided into 6 groups with 30 males. Each groups were administered with the placebo, extract of *Butea superba*, extract of *Mucuna collettii*, or combination of extract of *Butea superba* and extract of *Mucuna collettii* as following Table 1. The amount of administration was divided into two equal parts and administered twice a day, e.g., after breakfast and supper. The period of experiment was two months. The results are given in Table 2 as below.

【Table 1】

Group No.	Administration contents		
	placebo	Butea superba	Mucuna collettii
1	400mg/day	-	-
2	-	400mg/day	-
3	-	300mg/day	100mg/day
4	-	200mg/day	200mg/day
5	-	100mg/day	300mg/day
6	-	-	400mg/day

【Table 2】

	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6
No. of Subjects	30	30	30	30	30	30
1 st Erection Day after administration (day) (mean \pm S.D.)	22.36 \pm 2.01	7.39 \pm 1.05	4.23 \pm 0.89	2.19 \pm 0.74	4.56 \pm 0.92	9.51 \pm 1.20
Immediate Erection	10	21	24	28	23	19
Continuous Erection	10	18	23	27	21	15
Erection Maintenance for 2 mins. after Ejaculation	10	9	13	20	12	7
Weekly frequency of erection/remarkably increasing	0	20	24	27	22	16
Weekly Nos. of intercourse/remarkably increasing	0	7	10	16	9	5
Satisfaction in sexual activity	0	22	26	29	24	19

There was obtained a remarkably greater therapeutic effect on erection dysfunction or malfunction when Butea superba was used in combination with Mucuna collettii than alone.

4. Effect of Butea superba, Mucuna collettii and combination thereof on male with erection dysfunction upon topical application

It was determined whether gels containing the extracts of Butea superba, Mucuna collettii and combination thereof have an effect on erection dysfunction on 180 male patients with erection dysfunction, who were 20~55 years old.

180 males divided into 6 groups with 30 males. Each group was applied to the penis with the gel containing no any extract; and gels containing extract of Butea superba, extract of Mucuna collettii, and combination of extract of Butea superba and extract of

Mucuna collettii as following Table 3. The amount of application was divided into two equal parts and applied to the penis twice a day, e.g., morning and night. The period of experiment was one month. The results are given in Table 4 as below.

【Table 3】

Group No.	Extract contained in gel	
	<i>Butea superba</i>	<i>Mucuna collettii</i>
Group 1	-	-
Group 2	400mg/day	-
Group 3	300mg/day	100mg/day
Group 4	200mg/day	200mg/day
Group 5	100mg/day	300mg/day
Group 6	-	400mg/day

【Table 4】

Group No.	Total No. of Subjects	No. of Restored Male
Group 1	30	1
Group 2	30	19
Group 3	30	23
Group 4	30	27
Group 5	30	22
Group 6	30	16

5. Cutaneous allergy assay of *Butea superba* and *Mucuna collettii*

For cutaneous allergy assay, the extracts of *Butea superba* and *Mucuna collettii* were applied to the skin of six rats respectively. The results are given in Table 5 as below.

【Table 5】

	<i>Butea superba</i>	<i>Mucuna collettii</i>
1 st Allergic Response	No	No
2 nd Allergic Response	No	No